Rehabilitation interventions for improving physical and psychosocial functioning after hip fracture in older people (Protocol)

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[Intervention Protocol]

Rehabilitation interventions for improving physical and psychosocial functioning after hip fracture in older people

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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

To evaluate the short (four months or less) and longer term effects of interventions, including programmes, specifically aimed at improving and restoring physical and psychosocial functioning after a hip fracture in older people.

The primary comparison will be between any relevant intervention versus no or placebo (sham) intervention, or conventional or usual care.

BACKGROUND

Description of the condition

Hip fractures are amongst the most devastating consequences of osteoporosis and injurious accidental falls with 25-35% of patients dying in the first year post-fracture (Braithwaite 2003; Dzupa 2002), and only 40% returning to pre-fracture level of mobility (Koval 1994). Liebson 2002 reported that by one-year, 20% of patients living in the community before their hip fracture had moved to a nursing home, and another 15% had died.

Description of the intervention

Recovery can be difficult in frail older adults sustaining a hip fracture. Older adults who suffer hip fractures often require extensive health system resources (Ray 1997; Schneider 1990). In addition to the financial burdens to health systems, hip fractures have other costs to patients and their families and, in particular, they have a negative impact on health related quality of life measures (Adachi 2001).

Effective rehabilitation strategies for hip fractures are still evolving but evidence suggests that early multidisciplinary care improves clinical outcomes and reduces costs. A non-Cochrane systematic review of randomised controlled trials (RCTs) comparing multidisciplinary rehabilitation with usual orthopaedic care following hip fracture found that rehabilitation was associated with a modest but important reduction in poor outcome (Halbert 2007). Guidelines for the management of hip fracture from several countries promote the services of organised multidisciplinary health care teams (ASGM 2004; British Orthopaedic Association 2007), prompt surgery, early mobilisation and a team-based rehabilitation approach to restoring function. However, while it is recognised that the process is dependent on the co-ordinated skills of multiple professionals, concerns exist around the contribution of various components of this resource-intensive approach. Cochrane reviews examining mobilisation strategies (Handoll 2007) and nutritional supplementation (Avenell 2006) are available but it remains unclear what contribution is made by interventions specifically focused on improving independence with daily activities such as dressing, going shopping and interacting in the community. Social and psychological factors such as fear of falling, self-efficacy, perceived control and coping strategies are now thought to be important in the recovery from hip fracture but there is still limited information on how treatments impact on these factors (Mossey 1989; Oude Voshaar 2006; Proctor 2008). Furthermore there is little information on who can best provide these interventions.

Why it is important to do this review

Rehabilitation is usually defined as services provided by a multidisciplinary team with the goal of reducing disability by improving task-oriented behaviour (Cameron 2008). The benefits of inpatient multi-disciplinary rehabilitation for older people after hip fracture has been explored in a previous Cochrane review (Cameron 2001) and an update of this review, which has been extended to include post-hospital-discharge rehabilitation also, is in progress (Cameron 2008). However, Cameron 2001 provides very limited information to guide policy and practice regarding the effects of single interventions. Our review, which will complement the above review, will evaluate any single rehabilitative therapy (e.g. occupational therapy) across any setting (e.g. inpatient or ambulatory) which is specifically aimed at improving physical and psychosocial functioning after hip fracture. It will specifically not include mobilisation strategies (Handoll 2007).

Furthermore, previous research tends to focus on physical function as an outcome rather than psychosocial functioning. 'Positive affect' (e.g. having an optimistic outlook) is a significant independent predictor of recovery in activities of daily living in various clinical groups including hip fracture (Mossey 1989) and has been associated with significantly lowering the risk of frailty (Ostir 2004). Mastery or internal control has been demonstrated to be associated with better coping, adjustment and general mental health after hip fracture (Reich 1991). However, it is unclear whether therapy directed at these areas can achieve improvements in function and quality of life.

This review will examine evaluations of single therapy programmes, not covered elsewhere, that are specifically designed to improve physical and psychosocial functioning of older persons following hip fracture. This approach is modelled on the work in the area of stroke where, following a stroke, a broad range of programmes addressing physical and psychosocial functioning, such as occupational therapy and nursing, have been identified as helpful (Stroke Unit Trialists' Collaboration 2007).

OBJECTIVES

To evaluate the short (four months or less) and longer term effects of interventions, including programmes, specifically aimed at improving and restoring physical and psychosocial functioning after a hip fracture in older people.

The primary comparison will be between any relevant intervention versus no or placebo (sham) intervention, or conventional or usual care.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised or quasi-randomised (e.g. allocation by date of birth) studies that evaluate interventions designed to improve physical

or psychosocial functioning compared to usual or conventional care as described by the trialists. Cluster randomised trials where people are allocated to the different interventions in clusters (e.g. by hospital ward) will also be included.

Types of participants

The main study population is older people with any type of fracture of the proximal femur. Most participants will be aged 65 years or over and will have had surgery for their hip fracture. Trials that include younger participants will be included if the mean age minus one standard deviation is greater than 65 years. Participants younger than 65 years will be included as long as the number of these is relatively small and there was adequate randomisation of younger patients to intervention and control groups. Studies which focus on younger people with hip fracture will be excluded, as will trials involving people with multiple trauma.

Types of interventions

We will include studies evaluating interventions or programmes designed to improve and restore physical and psychosocial functioning after hip fracture surgery in older people. These interventions can be either single or multi-component and could be commenced at any stage after the injury. To be included, the studies focusing on physical functioning will need to report on interventions such as patient assessment, home assessment and assisting/training patients to perform key functional activities (e.g. washing, dressing). Also included will be studies evaluating practical measures such as provision of assistive devices/equipment and training to use these. The included studies on psychosocial functioning will examine interventions such as behavioural modification (e.g. to enhance motivation, increase confidence, counter fear of falling, and help orientation) or interventions relating to social support and inclusion (e.g. involvement, social care provision, arranging and enhancing support networks, training and support of carers, and encouraging social participation). Although many of these activities could be performed or initiated by an occupational therapist, it is the interventions rather than care providers that are the primary focus of this review. Nonetheless, the provision or extent of provision or timing of occupational therapy would be included in this review. We will include trials evaluating referral for treatment, perhaps as part of functional and psychosocial assessment, for clinical conditions such as depression but not those testing the actual treatment of clinical conditions such as depression.

We will include only trials comparing the rehabilitation intervention with either no or placebo intervention, or with usual or conventional care. Comparisons of different interventions will be included but not those comparing unusual or unconventional treatments only.

Studies that report on interventions that are pre-surgical only will be excluded. We will not include trials specifically testing mobilisation strategies as these are already reviewed in Handoll 2007. We will approach the authors of other Cochrane reviews (e.g. those for multidisciplinary rehabilitation, nutritional supplementation or mobilisation strategies using physiotherapy) to discuss the inclusion of any potentially eligible studies that appear to overlap with the scope of their reviews.

Types of outcome measures

Primary outcomes

The primary outcomes will include independence for physical function and quality of life (overall and independent domains) for psychosocial function. Preference will be given to validated, patient-reported outcome measures.

Secondary outcomes

Other measures of interest will include mobility, falls and fear of falling, strength and balance for physical function, pain and self-efficacy, self-rated health and well being, anxiety and depression for psychosocial function. Mortality and complications will also be collected. Adherence to education strategies will be examined as will health service outcomes such as services required, discharge destination, readmission to hospital and length of hospital stay.

Timing of outcome assessment

Where possible, outcome assessment will be carried out for the:

- short term (within four months of surgery); and
- longer term (one year or longer after surgery).

Search methods for identification of studies

Electronic searches

We will search the Cochrane Bone, Joint and Muscle Trauma Group Specialised Register, the Cochrane Central Register of Controlled Trials (CENTRAL) (current issue), MEDLINE (2004 onwards), EMBASE (2006 onwards), PsychINFO (1967 onwards), Latin American and Caribbean Health Sciences (LILACS) (1982 onwards), Allied and Complementary Medicine (AMED) (1985 onwards), Cumulative Index to Nursing and Allied Health Literature (CINAHL) (1982 onwards) and the Physiotherapy Evidence Database (PEDro) (1929 onwards). We will also search CurrentControlledTrials and the WHOInternational ClinicalTrialsRegistry for ongoing and recently completed trials. Abstracts will be included. There will be no language or time restrictions applied.

In MEDLINE (OvidSP), the subject specific search will be combined with the Cochrane Highly Sensitive Search Strategy for identifying randomised trials in MEDLINE: sensitivity- and precision-maximizing version (Lefebvre 2008) (Appendix 1), and will be modified for use in the other databases.

Searching other resources

Results from a comprehensive search for trials (up to August 1998) for a non-Cochrane review on rehabilitation following fractures in older people (Cameron 2000) will be screened as well as those

from a more recent non-Cochrane review on multidisciplinary rehabilitation (Halbert 2007). We will also handsearch the following publications: supplements of Acta Orthopaedica Scandinavica (1998 to 2004) and the Journal of Bone and Joint Surgery (British Volume) (1996 to 2008). The proceedings of the British Orthopaedic Association Congress (1996 to 2003), SICOT (1996 to 1999) and the annual meetings of the American Orthopaedic Trauma Assocation (1996 to 2008) will also be handsearched. Additionally, "Fracture" articles will be downloaded weekly from new issues of 15 publications (Acta Orthop Scand; Am J Orthop; Arch Orthop Trauma Surg; Clin J Sport Med; Clin Orthop; Foot Ankle Int; Injury; J Am Acad Orthop Surg; J Arthroplasty; J Bone Joint Surg Am; J Bone Joint Surg Br; J Foot Ankle Surg; J Orthop Trauma; J Trauma; Orthopedics).

Data collection and analysis

Selection of studies

Two review authors (KU and MC) will independently screen papers identified from the database searches. The same two review authors will then assess the trials based on the pre-defined inclusion criteria. Reasons for exclusion will be documented. A third review author (MM) will moderate any disagreements. Further information about study methods and interventions will be sought from trial authors if necessary. From the full text, trials which meet the selection criteria will be selected for inclusion. Trials that aim to improve physical and psychosocial function will be included in either this review or in the review of multidisciplinary interventions for older people following hip fracture, but not both reviews. This will be determined by negotiation between the authors of the two reviews. We will approach the authors of other Cochrane reviews to discuss the inclusion of any potentially eligible studies that appear to overlap with the scope of their review.

Data extraction and management

A pre-designed data extraction form will be used by two independent reviewers to evaluate the selected studies. The data extraction form will be piloted on two trials and relevant changes will be made in response to the findings of the pilot. The remaining studies will then be evaluated. Data will be collected on study design characteristics, the study population, interventions, outcome measures, and length of follow-up. Information will also be gathered on the discipline administering the intervention (e.g. occupational therapy, nursing) and whether they directly deliver the intervention or have a facilitatory role only (e.g. referral to existing services). Trial authors will be contacted for clarification when necessary. Disagreements will be resolved by a third review author.

Assessment of risk of bias in included studies

The Cochrane Collaboration's tool for assessing risk of bias will be used by two independent review authors to assess the methodological quality of studies included in the review (*see* Appendix 2). This tool incorporates assessment of randomisation (sequence generation and allocation concealment), blinding, completeness of outcome data, selection of outcomes reported and other sources of bias (e.g. intention-to-treat analysis). Other sources of bias will include selection bias, where we will assess the risk of bias from imbalances in key baseline characteristics (e.g. cognitive impairment). We will also explore attrition bias to determine whether there are differences in drop outs between groups. After piloting the risk of bias tool for two trials, the review authors responsible for data extraction will discuss any modifications that may be required to enhance the assessment of risk of bias.

Measures of treatment effect

Outcome measures will be classified in terms of domain assessed, e.g. psychologic or social. Clinically relevant cut-off points will be identified. Results will be analysed at both short term (four months or less) and longer term (one year or longer) intervals. Patient and caregiver results will be presented separately. Risk ratios with 95% confidence intervals will be calculated for dichotomous outcomes. Mean differences with 95% confidence intervals will be calculated for continuous outcomes.

Unit of analysis issues

The unit of randomisation in these trials is usually the individual patient. However, we will also include cluster randomised trials where the unit of randomisation is another entity such as a hospital ward. Appropriate adjustments will be made before presenting data from such trials. We will seek advice on the interpretation and presentation of the results from such trials from the statistical editors of the Cochrane Bone, Joint and Muscle Trauma Review Group.

Dealing with missing data

Where possible we will perform intention-to-treat analyses to include all people randomised. However, where drop-outs have been identified, the actual denominator of subjects contributing data at the relevant outcome assessment will be used. We will investigate the effect of drop outs and exclusions by conducting worse and best scenario sensitivity analyses. We will be alert to the potential mislabelling or non identification of standard errors and standard deviations. Unless missing standard deviations can be derived from confidence intervals, P values or standard errors, we will not assume values in order to present these in the analyses.

Assessment of heterogeneity

Heterogeneity will be assessed by visual inspection of the forest plot (analysis) along with consideration of the chi^2 test for heterogeneity and the I^2 statistic (Higgins 2003). Subgroup analyses will be performed and impact on heterogeneity described. It is anticipated that we will pool data even if heterogeneity remains high.

Assessment of reporting biases

If sufficient data are available, we will attempt to assess publication bias by preparing a funnel plot. Our search of clinical trials registers should assist in decreasing publication bias. We will also

investigate selective outcome reporting by comparing the study outcomes with those routinely presented for similar studies and also by comparing the methods section of papers with the results reported.

Data synthesis

If considered appropriate, results of comparable groups of trials will be pooled. Initially we will use the fixed-effect model and 95% confidence intervals. We will also consider using the random-effects model, especially where there is unexplained heterogeneity. Outcomes identified as being measured using different instruments and/or with different scales across studies will be pooled using standardised mean difference. Mindful of unit of analysis issues, and where appropriate adjustments were or can be made, we will pool the data from cluster randomised trials using the generic inverse variance option.

Subgroup analysis and investigation of heterogeneity

Sub-group analysis will be performed to determine whether outcomes vary according to cognitive status (dementia or chronic cognitive impairment versus no dementia or chronic cognitive impairment), pre-injury functional status (independent in activities of daily living versus dependent in activities of daily living), pre-injury accommodation status (residential facility versus private dwelling), duration of intervention (4 months or less versus >4 months) and intervening discipline (e.g. nursing versus occupational therapy).

Sensitivity analysis

Where possible, the review authors will perform sensitivity analyses to examine the effects of important sources of bias, such as whether allocation was concealed, in the included studies.

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* *Indicates the major publication for the study*

APPENDICES

Appendix 1. MEDLINE search strategy

1. exp Femur/
2. Fractures, Bone/ or exp Fracture Fixation/ or Fracture Healing/
3. 1 and 2
4. ((hip* or pertrochant* or intertrochant* or trochanteric or subtrochanteric or extracapsular* or ((femur* or femoral*) adj3 (neck or proximal))) adj4 fracture*).tw.
5. exp Human Activities/
6. Quality of Life/
7. Social Support/
8. exp "Outcome and Process Assessment (Health Care)"/
9. Health Facilities/or Ambulatory Care Facilities/ or Community Health Centres/ or Outpatient Clinics, Hospital/ or Rehabilitation Centres
10. Hospitals, Convalescent/ or Hospitals, Osteopathic/
11. Community Health Services/ or Community Health Nursing/ or Counselling/ or Home Care Services, Hospital-Based/ or Health Services For The Aged/ or Social Work/ or Exp Nursing Care/ or Home Care Services/ or Home Nursing/
12. Hospitals, Community/ or Hospitals/
13. exp Comprehensive Health Care/ or Continuity of Patient Care/ or Patient Care Team/
14. (functional status or functional outcome* or ambulation).tw.
15. exp Health Status/ or Recovery of Function
16. Rehabilitation Nursing/
17. ((geriatric or inter?disciplinary or multi?disciplinary or early or post?operative or post?surgical or home* or intensive or accelerated or intervention or functional) adj2 (intervention or care or rehabilitation or program* or approach or group or recovery)).tw
18. Rehabilitation/ or Early Ambulation/ or Exp Exercise Therapy/ or Occupational Therapy/ or Rehabilitation, Vocational/
19. Health Education/ or Patient Education as Topic/
20. Patient Care/ or Aftercare/ or Ambulatory Care/ or Day Care/ or Postoperative Care/
21. Postoperative Period/
22. Outpatients/
23. Social Adjustment/ or Adaptation, Psychological/
24. Mental Health/
25. Self Efficacy/
26. psychosocial.tw
27. Or/5-25
28. exp Aged/ or Middle Aged/
29. older people.mp.
30. geriatr*.mp.
31. 28 or 29 or 30
32. Randomized Controlled Trial.pt.
33. Controlled Clinical Trial.pt
34. randomized.ab.
35. placebo.ab.
36. Clinical Trials as Topic/.
37. randomly.ab.
38. trial.ti.

39. Humans/
40. 32 or 33 or 34 or 35 or 36 or 37 or 38
41. 39 and 40
42. (3 or 4) and 27 and 31 and 41

Appendix 2. Risk of Bias Assessment Tool

Domain	Description	Review authors judgement
Sequence generation	Describe the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups.	Was the allocation sequence adequately generated?
Allocation concealment	Describe the method used to conceal the allocation sequence in sufficient detail to determine whether intervention allocations could have been foreseen in advance of, or during, enrolment.	Was allocation adequately concealed?
Blinding of participants, personnel and outcome assessors *Assessments should be made for each main outcome (or class of outcomes).*	Describe all measures used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. Provide any information relating to whether the intended blinding was effective.	Was knowledge of the allocated intervention adequately prevented during the study?
Incomplete outcome data *Assessments should be made for each main outcome (or class of outcomes).*	Describe the completeness of outcome data for each main outcome, including attrition and exclusions from the analysis. State whether attrition and exclusions were reported, the numbers in each intervention group (compared with total randomized participants), reasons for attrition/exclusions where reported, and any re-inclusions in analyses performed by the review authors.	Were incomplete outcome data adequately addressed?

(*Continued*)

Selective outcome reporting	State how the possibility of selective outcome reporting was examined by the review authors, and what was found.	Are reports of the study free of suggestion of selective outcome reporting?
Other sources of bias	State any important concerns about bias not addressed in the other domains in the tool. If particular questions/entries were pre-specified in the reviews protocol, responses should be provided for each question/entry.	Was the study apparently free of other problems that could put it at a high risk of bias?

HISTORY

Protocol first published: Issue 1, 2009

DECLARATIONS OF INTEREST

It is possible that the authors may have been involved in a study included in the review. In this case the paper will be appraised by other independent review authors.

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Internal sources

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